UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* Robert Hindin, Plaintiff-Relator, v. AETNA, INC., EXPRESS SCRIPTS HOLDING COMPANY, CVS CAREMARK, WALMART, INC., WALGREENS BOOTS ALLIANCE, INC., CVS HEALTH, CORP., CIGNA, WELLCARE HEALTH PLANS, INC., CENTENE CORPORATION, INC. Defendants.	**FILED UNDER SEAL** **DO NOT PLACE ON PACER** **JURY TRIAL DEMANDED**

I. PRELIMINARY STATEMENT

Pursuant to the Federal False Claims Act ("FCA"), 31 U.S.C. § 3729, et seq., Plaintiff-Relator Robert Hindin hereby brings this action against (i) Aetna, Inc., (ii) Express Scripts Holding Company, (iii) CVS Caremark, (iv) Walmart, Inc., (v) Walgreens Boots Alliance, Inc., (vi) CVS Health, Corp.[1] (vii) Cigna,[2] (viii) WellCare Health Plans, Inc.,[3] and (ix) Centene Corporation (collectively, "Defendants").[4]

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[1] CVS Health acquired Aetna in November 2018, and on information and belief, acquired their potential legal liabilities as well. https://www.pharmacytimes.com/view/cvs-finalizes-acquisition-of-aetna-and-looks-to-the-future.

[2] Cigna and Express Scripts merged in December 2018, and on information and belief, acquired their potential legal liabilities as well. https://www.modernhealthcare.com/article/20181220/NEWS/181229999/cigna-and-express-scripts-close-on-67-billion-merger.

[3] As part of the CVS Health's acquisition of Aetna, Aetna divested its Part D plans to WellCare Health Plans, Inc., which likely includes the liability associated with these plans, implicating them in the violative conduct at the core of this Amended Complaint. https://www.healthleadersmedia.com/welcome-ad?toURL=/strategy/wellcare-acquires-aetnas-part-d-health-plans-cvs-aetna-hits-rumble-strip.

[4] Centene Corporation acquired WellCare Health Plans, Inc. on March 2019, and on information and belief, acquired their potential legal liabilities as well.

1. Medicare Part D prescription drug coverage is provided to Medicare patients by private insurance companies. The companies, known as Part D "Sponsors," are required to follow a series of regulations that govern the Medicare Part D program.

2. One of the most important regulations involves the prices offered to Medicare enrollees. Specifically, 42 C.F.R § 423.104 (g)(l) requires ***all Part D Sponsors*** to offer "Negotiated Prices" to their enrollees for Part D covered drugs. § 423.104 (g)(l). "Negotiated Prices" means prices for covered Part D drugs that satisfy each of the following elements:

> (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as to the amount such network entity will receive, in total, for a particular drug.
>
> (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and
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> (3) Include any dispensing fees; but
>
> (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale.
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> (5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part. 42 C.F.R. § 423.100.

In other words, Negotiated Prices are the result of arms' length bargaining between Sponsors and their trading partners. These prices reflect the massive bargaining power wielded by Sponsors like Aetna, Inc. ("Aetna") and pharmaceutical benefits managers ("PBMs") like Express Scripts Holding Company ("Express Scripts"). Using their power to provide these low prices to Medicare patients is critical to the functioning of the Medicare Part D program.

3. Notwithstanding this fundamental requirement and the patient-based fiscal purpose which animates it, Aetna and Express Scripts—in direct violation of the law—consistently fail to

provide their Medicare enrollees with the Negotiated Prices for the drugs they cover. Like Aetna and Express Scripts, CVS Caremark ("Caremark")—which is Aetna's PBM—consistently violates the law by failing to ensure Aetna's Medicare Part D enrollees receive the Negotiated Prices.

4. For the reasons detailed below, each time Aetna, Express Scripts, and Caremark failed to provide Negotiated Prices to their Medicare Part D enrollees, the FCA was (and is) violated.

5. Walmart, Inc. ("Walmart") and Walgreens Boots Alliance, Inc. ("Walgreens") are (or have) pharmacies that contract with entities such as PBMs to provide prescriptions to Medicare Part D enrollees, and who—like each entity involved in providing Medicare Part D benefits—are legally obligated to provide said enrollees with the Negotiated Prices for their prescriptions.

6. Notwithstanding these obligations, Walmart and Walgreens consistently overcharge Aetna and Express Scripts' Medicare Part D enrollees by failing to charge them the Negotiated Prices for their prescriptions. Each time Walmart and Walgreens failed to charge enrollees the Negotiated Prices, the FCA was (and is) violated.

7. In all, the FCA violations perpetuated by Aetna, Express Scripts, Caremark, Walmart, and Walgreens have conservatively cost the Federal Government approximately **$250 million from 2015 to 2019.**[5]

II. THE PARTIES

8. **Plaintiff-Relator**. Robert Hindin ("Relator" or "Mr. Hindin") is an individual who resides in Andover, Massachusetts and has been covered by Medicare Part D since May 1, 2015.

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[5] See Exhibits A, B, and C for (i) an overview of the Damages, and (ii) supporting documents from Professor Andrew Swift—an Associate Professor of Statistics, Probability, and Operations Research at the University of Nebraska (Omaha)—who also provided the final calculations for this Complaint. Given that Relator suspects alleged conduct is still occurring, it is likely the Federal Government has paid tens of millions more since the beginning of 2020.

9. **The Government**. Relator brings this action on behalf of the United States (the "Government") pursuant to the *qui tam* provisions of the federal FCA, 31 U.S.C. § 3729 et seq., to seek recovery for damages to the Medicare Part D program, which was established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395w-101 et seq. The Centers for Medicare and Medicaid Services ("CMS") of the U.S. Department of Health & Human Services ("HHS") fund and oversee the Medicare Part D program. Their key responsibilities include providing each Medicare Part D "Plan Sponsor" (the insurers) with advanced monthly payments for enrollees, 42 C.F.R. § 423.293, and to hold Plan Sponsors and their subcontractors accountable to all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1); 42 C.F.R. § 423.505(i)(4)(iv).

10. **Defendants**:

a. **Aetna, Inc**. "Aetna" is a managed healthcare company that sells insurance plans and related services and is headquartered in Hartford, Connecticut. Since November 28, 2018, Aetna has been a subsidiary of CVS Health.

b. **Express Scripts, Inc**. "Express Scripts" is a PBM that provides its own insurance plans, as well as a variety of intermediary services, such as contract negotiations, formulary management, and payment processing services, and is headquartered in St. Louis, Missouri. Since December 20, 2018, Express Scripts has been a subsidiary of Cigna.

c. **CVS Caremark**. "Caremark" is a PBM that also provides a variety of intermediary services, such as contract negotiations, formulary management, and payment processing services, and is headquartered in Woonsocket, Rhode Island. During the relevant time, Caremark was the PBM for Aetna.

d. **Walmart, Inc**. "Walmart" is a multinational retail corporation that operates a chain of supermarkets and pharmacies and is headquartered in Bentonville, Arkansas. Walmart is publicly traded on the New York Stock Exchange and had a market capitalization of $382.42 billion as of December 2, 2021.[6]

e. **Walgreens Boots Alliance, Inc**. "Walgreens" is a retail pharmacy company headquartered in Deerfield, Illinois. Walgreens is publicly traded on the

[6] https://finance.yahoo.com/quote/WMT/

NASDAQ stock exchange and had a market capitalization of $37.85 billion as of December 2, 2021.[7]

f. **WellCare Health Plans, Inc.** "WellCare" is a health insurance company focusing on managed care services through Medicaid, Medicare Advantage, and the Medicare Prescription Drug program and headquartered in Tampa, Florida. As part of the CVS Health's acquisition of Aetna, Aetna had to divest its Part D plans to WellCare Health Plans, Inc., which likely includes the liability associated with these plans, implicating them in the violative conduct at the core of this Amended Complaint.

g. **Centene Corp**. "Centene" is a health services organization and a major insurance provider headquartered in St. Louis, Missouri. Centene is publicly traded on the New York Stock Exchange and had a market capitalization of $40.95 billion as of December 2, 2021.[8] Centene acquired WellCare on March 2019, and on information and belief, also acquired its potential legal liabilities.

h. **Cigna Healthcare, Inc**. "Cigna" is a health services organization and a major insurance provider headquartered in Bloomfield, Connecticut. Cigna is publicly traded on the New York Stock Exchange and had a market capitalization of $64.54 billion as of December 2, 2021.[9] Cigna and Express Scripts merged on December 2018, and on information and belief, acquired their potential legal liabilities as well.

i. **CVS Health, Corp**. "CVS Health" is a healthcare company headquartered in Woonsocket, Rhode Island. CVS Health is publicly traded on the New York Stock Exchange and had a market capitalization of $117.56 billion as of December 2, 2021.[10] CVS Health acquired Aetna on November 2018, and on information and belief, also acquired its potential legal liabilities.

III. JURISDICTION AND VENUE

11. Pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action, which arises under the FCA, 31 U.S.C. § 3729, et seq. The FCA also confers jurisdiction upon this Court pursuant to 31 U.S.C. § 3732(b).

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[7] https://finance.yahoo.com/quote/WBA/
[8] https://finance.yahoo.com/quote/CNC/
[9] https://finance.yahoo.com/quote/CI/
[10] https://finance.yahoo.com/quote/CVS/

12. Personal jurisdiction and venue are proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because each Defendant transacts business in this judicial district, including by selling insurance plans, operating pharmacies, and negotiating contracts between insurers and pharmacies.

13. In June 2018, Relator voluntarily disclosed to the Government the information on which the allegations and/or transactions described herein are based within the meaning of 31 U.S.C. § 3730(e)(4)(B).

14. Relator is unaware of any public disclosure of the allegations or transactions that form the basis of this Amended Complaint within the meaning of 31 U.S.C. § 3730(e)(4)(A). In the event there has been a public disclosure as defined in 31 U.S.C. § 3730(e)(4)(A), Relator is an original source within the meaning of 31 U.S.C. § 3730(e)(4)(B).

IV. LEGAL AND REGULATORY BACKGROUND

a. The False Claims Act

15. The FCA "was passed in 1863 as a result of investigations of the fraudulent use of government funds during the Civil War." U.S. v. Neifert-White Co., 390 U.S. 228, 232 (1968). Furthermore, the FCA created "a scheme that permits either the Attorney General or a private party to initiate a civil action alleging fraud on the Government," U.S. ex rel. Eisenstein v. City of New York, NY., 556 U.S. 928, 932 (2009) (citations omitted), while imposing "significant penalties on those who defraud the Government." Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1995 (2016).

16. As relevant here, the FCA establishes treble damages liability for the Government where an individual or entity:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A);

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id*. § 3729(a)(1)(B); or

c. "conspires to commit a violation of subparagraph (A), (B)…" *id*. § 3729(a)(1)(C).

17. The terms "knowing" and "knowingly" mean "that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). However, proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

18. The term "claim" means "any request or demand, whether under a contract or otherwise, for money or property, and whether or not the United States has title to the money or property that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded…" 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

19. The term "material" means having "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

20. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 and 64 Fed. Reg. 47099, 47103 (1999), civil monetary penalties under the FCA are $5,500 to $11,000 for violations occurring on or after September 29, 1999, but on or before November 2, 2015. *See* 28 C.F.R. § 85.3.

21. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and 83 Fed. Reg. 706 (Jan. 8, 2018), civil monetary penalties under the FCA have been adjusted to $11,181 to $22,363 for violations occurring on or after November 2, 2015 that have been assessed after January 29, 2018. *See* 28 C.F.R. § 85.5.

b. <u>Medicare Part D</u>

22. Since January 1, 2006, Medicare has subsidized outpatient prescription drug payments for persons eligible for Medicare Part D coverage—a service added to Medicare by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, ("MMA"), Pub, L. 108-173 (Dec. 8, 2003), 42 U.S.C. § 1395w–101 et seq.

1. <u>Medicare Part D: Plan Sponsors</u>

23. Congress' central purpose in creating Medicare Part D was to make medication affordable for all eligible enrollees, particularly for the millions of qualified, low-income enrollees who would otherwise be unable to afford their prescriptions.[11]

24. To bridge the gap between enrollees and affordable access to medicine, Medicare Part D grants private insurance companies ("Sponsors") the privilege of administering the Part D benefit. CMS, the Government agency responsible for managing Part D, contracts only with Sponsors, 42 U.S.C. § 1395w–112(b)(1), and healthcare providers do not bill the Government directly for services provided to Part D enrollees. Instead, they bill the enrollees and their Sponsors; the Sponsors, in turn, are reimbursed by CMS.

25. To receive Part D coverage, Medicare enrollees sign up for one of hundreds of private Part D Plans offered by Sponsors, such as those offered by defendants Aetna and Express

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[11] Suzanna M. Kirchhoff, *Medicare Part D Prescription Drug Benefit*, Congressional Research Service, Dec. 18, 2020, pgs. 6-7 (https://crsreports.congress.gov/product/pdf/R/R40611).

Scripts. 42 U.S.C. 1395w-101 through 1395w-153, and 1395hh. To become a Sponsor, a private insurer submits a certified application to CMS. 42 C.F.R. §§ 423.502, 423.265, 423.272. If accepted, the bid lasts for one year, and the insurer must reapply each year it wants to be a Sponsor.

26. Sponsors must agree to comply with the requirements and standards of Part D, including all of the terms and conditions of payment. Section 1860D-12, 42 U.S.C. § 1395w-112(b)(1). Each Sponsor expressly "agrees to comply with Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to: applicable provisions of Federal criminal law [and] the False Claims Act (32 U.S.C. §§ 3729 et seq.)," 42 C.F.R. 423.505(h)(1), such as the requirement to explicitly certify data each month as a condition for receiving monthly capitated payments from CMS, 42 C.F.R. § 423.505(k), and the promise to protect enrollees from incurring any financial obligations that are the Sponsors' responsibility, ***such as paying the full Negotiated Price for a prescription when the Sponsor is obligated to cover part of the fee***. 42 C.F.R. § 423.505(g) (emphasis added).

27. Sponsors offer a variety of plans, including prescription drug plans ("PDPs"), Medicare Advantage prescription drug plans ("MA-PD plans"), and a Program of All-Inclusive Care for the Elderly ("PACE"). 42 C.F.R. § 423.4. Regardless of which plans a Sponsor offers, the Sponsor must provide qualified prescription drug coverage, including "standard prescription drug coverage" or "alternative prescription drug coverage" with (at minimum) actuarially equivalent benefits. 42 U.S.C. § 1395w-102; 42 C.F.R. §§ 423.104(c); 423.104(d)(3).

2. Medicare Part D: Plan Sponsor Subcontractors

28. Part D Sponsors often contract with other entities to provide full services to their enrollees. 42 C.F.R. § 423.505(i). CMS lists the eligible entities with whom Sponsors can work, which includes pharmacies or other providers, related entities, contractors, subcontractors, "first

tier entities," and "downstream entities."[12] 42 C.F.R. § 423.505. These entities can perform functions on behalf of the Sponsors, such as providing health and administrative services (e.g., pharmacies and the pharmacist) or helping to negotiate contracts between manufacturers, insurers, and pharmacies (e.g., PBMs).

29. As a condition of contracting with the Sponsor—or contracting with an entity that has contracted with the Sponsor—each and every entity is obligated to comply with all applicable laws, regulations, and CMS instructions ***just as if it were a Sponsor***. Therefore, both Sponsors and the entities with whom the Sponsors contract can be found liable for Medicare Part D violations.[13] 42 C.F.R. §423.505(i)(4)(iv) ("[E]ach and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.")

3. Medicare Part D: Enrollee Benefits

30. CMS pays Sponsors for each Part D beneficiary enrolled in the Sponsor's plans. These payments come in the form of capitated (i.e., flat) advanced monthly payments equal to the Part D plan's standardized bid, adjusted to account for each individual beneficiary's health status per § 423.329(b), minus a monthly beneficiary premium as determined in § 423.286. 42 C.F.R. § 423.315(b).

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[12] "First tier" entities are parties that enter into written agreements to provide administrative services or healthcare services for a Medicare eligible individual. First tier entities may contract with a "downstream entity," which is any entity below the level of the arrangement between a Sponsor and a first tier entity.

[13] United States v. CVS Caremark Corp., 2015 WL 5582553, at *5 (E.D. Pa. Sept. 22, 2015), aff'd on other grounds sub nom. United States ex rel. Spay v. CVS Caremark Corp., 875 F.3d 746 (3d Cir. 2017) ("CMS regulations require that all subcontracts between Part D plan Sponsors and downstream entities, including pharmacies and PBMs [PBMs are considered first tier entities], contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).")

31. When a pharmacy dispenses drugs to a Medicare Part D enrollee, it submits an electronic claim to the enrollee's Sponsor. In return, the pharmacy receives reimbursement from the Sponsor for the costs not paid by the enrollee.

32. The Part D Program requires Sponsors (or their agents) to submit to CMS an electronic record each time a drug is dispensed. This record is called a Prescription Drug Event ("PDE").[14] The PDEs submitted to CMS include the amount paid to the pharmacy by the Sponsor.[15]

33. At the end of the year, CMS uses the PDE data to perform a year-end "reconciliation" process to determine the level of cost-sharing between the Sponsor and CMS.[16] If a Sponsor's actual costs for the year exceed the estimated costs for the year, the Sponsor may be able to recoup some of its losses through a risk-sharing arrangement with CMS. Conversely, if the Sponsor's estimated costs exceed its actual costs, the Sponsor may have to pay back some of its unanticipated profit to CMS.

34. Most Medicare enrollees who elect Part D coverage are responsible for certain costs, which may include a monthly premium, an annual deductible, and co-pays/co-insurance. Some enrollees, such as those who qualify for a Low-Income Subsidy ("LIS"), can have their

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[14] 42 U.S.C.A. § 1395w-115(d)(2)(A) ("Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section."); 42 C.F.R. § 423.322(a) ("Payment conditional upon provision of information. Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law."); <u>CVS Caremark Corp</u>, at *7 (E.D. Pa. Sept. 22, 2015) (subsequent holdings omitted) ("The Part D Program requires Sponsors (or their agents) to submit to CMS a PDE record for 100% of the prescriptions dispensed to a Part D beneficiary.")

[15] See <u>CVS Caremark Corp</u>., at *6; https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/downloads/pdedataelements.pdf

[16] 42 C.F.R. §423.514(a) ("Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following (1) The cost of its operations. (2) The patterns of utilization of its services. (3) The availability, accessibility, and acceptability of its services. (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation. (5) Pharmacy performance measures. (6) Other matters that CMS may require.")

monthly premium waived and may receive extra help with annual deductibles and co-payments related to Medicare Part D covered drugs.[17]

35. After receiving a prescription from their doctor, a Part D enrollee can go to a retail pharmacy in the Sponsor's network of pharmacies and present the prescription to the pharmacist. The pharmacy receives both the prescription and the enrollee's information and then submits a claim for payment to the Sponsor (or, if the Sponsor has contracted with a PBM, to the Sponsor's PBM).

36. If the Sponsor confirms the claim is payable, the Sponsor pays the portion of the claim for which they are responsible. The enrollee then pays the deductible (if applicable) or the co-pay/co-insurance (if applicable) to the pharmacy, and the enrollee receives the prescription.

4. **Medicare Part D: Formularies and Covered Drugs**

37. A "formulary" includes all of the drugs covered by a Sponsor's plan and is developed by Sponsors in accordance with 42 C.F.R. § 423.4.

38. A "covered Part D drug" is a drug that is (a) "included in a Part D plan's formulary" or (b) is treated as being included in a Part D plan's formulary for certain reasons enumerated in the applicable regulations. See 42 C.F.R. § 423.100.

39. While there are certain drugs that are excluded at 42 U.S.C. § 1396r-8(d)(2-3), or are excluded from the definition of a Part D drug at 42 U.S.C. § 1395w-102(e)(2)(A), plans can still provide Part D prescription drug coverage for drugs not on the formulary if the patient and the patient's doctor request an exception.[18]

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[17] https://www.ssa.gov/benefits/medicare/prescriptionhelp.html
[18] https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover
("If you or your prescriber (your doctor or other healthcare provider who's legally allowed to write prescriptions) believes none of the drugs on your plan's formulary will work for your condition, you can ask for an exception.")

40. Sponsors negotiate prices for covered Part D drugs, which makes these drugs less expensive to enrollees. Access to these "Negotiated Prices" creates a major incentive for potential enrollees to choose one sponsor over another. In other words, if the drugs an enrollee needs are covered by a particular Sponsor's formulary, and the co-pays/co-insurance and monthly premiums are less than those offered by a competing Sponsor, then the enrollee will likely select the Sponsor offering the better coverage to save money. In fact, CMS encourages enrollees to take advantage of the many benefits that come with purchasing drugs covered by their Sponsors:

> Although beneficiaries can still purchase a covered Part D drug at a network pharmacy without using their Part D benefit or a supplemental card, CMS encourages beneficiaries to use their Part D benefit. **Use of the benefit affords beneficiaries access not only to the plan's negotiated prices, which in most cases are the lowest price available,** but also to the plan's drug utilization review and other safety edits that only can be provided when the plan adjudicates the claim.

<u>Medicare Prescription Drug Benefit Manual</u>, Chapter 14, Section 50.4.2. (emphasis added.)

41. Sometimes, enrollees have to pay the "full cost" for drugs on the formulary. This happens most commonly when an enrollee fills a prescription at a time when they have not met their deductible.

42. By way of illustration, Aetna states the following about "full cost" pricing prior to meeting the deductible: "[Y]ou must pay the full cost of your drugs until you reach the plan's deductible amount...**[y]our 'full cost' is usually lower than the normal full price of the drug, since <u>*our plan has negotiated lower costs*</u> for most drugs**." (emphasis added). Aetna EOC 2016, pg. 58 (Exhibit D).[19]

43. Thus understood, the "full cost" price charged to an enrollee is the price that the Sponsor negotiated, as opposed to the full retail cash price paid by the uninsured general public.

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[19] See 2016 Evidence of Coverage Template (Exhibit E), pg. 68. Review paragraphs 56 and 57 for an explanation for the importance of the Evidence of Coverage Templates, and how they should govern the Defendants' conduct.

44. Paying the full cost—meaning 100% of the Negotiated Price—can also occur with drugs that have a condition added by the Sponsor to which the enrollee must adhere (e.g., prior authorization, quantity limits, step therapy, etc.).[20] If such a condition causes the enrollee to pay 100% of the Negotiated Price at the pharmacy counter, once the enrollee satisfies the condition, the enrollee can seek payment from the Sponsor for the enrollee's out of pocket costs, less the co-payment or co-insurance as applicable, provided that the deductible has been satisfied.

45. For example, if a drug has a prior authorization requirement which has not been met as of the time that the beneficiary pays 100% of the Negotiated Price at the pharmacy counter, but is met ***after*** the money has been paid, the enrollee can seek reimbursement from the Sponsor.

46. Aetna explains to enrollees who pay 100% of the Negotiated Price for a drug that requires prior authorization: "Save your receipt and send a copy to us when you ask us to pay you back. In some situations, we may need to get more information from your doctor **in order to pay you back for *<u>our share of the cost</u>*.**"[21] (emphasis added).[22]

[20] Aetna EOC 2016 (Exhibit D), pg. 74; Exhibit E, pg. 90.
[21] Aetna EOC 2016, pg. 74; Exhibit E, pg. 90.
[22] CMS provides a model "Evidence of Coverage" for Plan Sponsors, which explains to enrollees that "special rules restrict how and when the plan covers" [i.e. help you pay for] certain prescription drugs. [CMS Model EOC 2020, pg. 120]. The purpose of these restrictions depends on the drug-in-question, but broadly speaking, these rules are for the insurer to "control overall drug costs" to keep drug coverage more affordable. By way of example, Express Scripts states the following: *"Utilization management ensures that less costly alternatives are prescribed first. This evaluation is done through a prior authorization (PA) process that checks that less expensive, clinically similar alternatives aren't overlooked. This helps plan sponsors prevent waste and keep treatment affordable for members."* (https://www.express-scripts.com/corporate/articles/how-always-improve-good-utilization-management).
These restrictions, therefore, are primarily for cost management purposes for drugs that are otherwise recognized as safe for use, since the insurer encourages the use of generic equivalents and trying less expensive drugs before more expensive drugs are prescribed despite having both on their formulary.

i. Enrollee Benefits: Negotiated Prices

47. As noted, one of the benefits that all Part D Sponsors must offer to enrollees is access to Negotiated Prices for covered drugs. § 423.104 (g)(l). "Negotiated Prices" means prices for covered Part D drugs that meet all of the following:

> (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.
>
> (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and
>
> (3) Include any dispensing fees; but
>
> (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale.
>
> (5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

42 C.F.R. § 423.100.

48. Also as noted, Negotiated Prices reflect the massive bargaining power Sponsors like Aetna, and PBMs like Express Scripts, wield on behalf of their enrollees, and they are therefore critical to the cost saving mechanisms for Medicare Part D.

49. Further, to the point of saving money for enrollees, the obligation to provide Negotiated Prices is plainly stated in the laws and regulations, including the obligation to provide Negotiated Prices ***even when the Sponsor is not paying for anything***, such as a prescription that is filled before the enrollee has met his/her deductible:

a. **42 U.S.C. § 1395w-102(d)(1)(A)**: "Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan…the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, **regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the**

application of a deductible or other cost-sharing or an initial coverage limit…" (emphasis added).

b. **<u>42 C.F.R. § 423.104(g)(l)</u>**: "A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices **for covered Part D drugs included in its Part D plan's formulary**." (emphasis added).

50. Consistent with these provisions, Negotiated Prices were central to the policy discussions that led to the creation of Medicare Part D (and its subsequent amendments). By way of example, less than one month before Medicare Part D became law, a "Joint Explanatory Statement" (Exhibit F) memorializing the agreements between the House and the Senate highlighted and emphasized the importance of Negotiated Prices:

a. "The program will rely on private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies will be provided to encourage participation. Plans will determine premiums through a bid process **and will compete based on premiums and negotiated prices**."[23]

b. "PDP sponsors are required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary **to assure access to negotiated prices for drugs**."[24]

c. "The New Section 1860D-2 specifies the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either 'standard prescription drug coverage' or 'alternative prescription drug coverage' with at least actuarially equivalent benefits. **In both cases, access would have to be provided to negotiated prices**."[25]

51. These principles (regarding Negotiated Prices being central to the purpose of the law) became law once the Medicare Part D statute was enacted on December 8, 2003. The portions of the statute reflecting these principles are excerpted below:

a. (1) In general. For purposes of this part and part C, the term 'qualified prescription drug coverage' means either of the following:

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[23] Exhibit F, pg. 4 (emphasis added).
[24] Exhibit F, pg. 21 (emphasis added).
[25] Exhibit F, pg. 11 (emphasis added).

a. (A) Standard prescription drug coverage with access to negotiated prices.—Standard prescription drug coverage (as defined in subsection (b)) and **access to negotiated prices** under subsection (d).

b. (B) Alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices.—Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and **access to negotiated prices** under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

42 U.S.C. § 1395w-102. In other words, these excerpts from the Joint Explanatory Statement are not some loose collection of statements, but instead provide sound legislative history for the proposition that providing Negotiated Prices is a material part of Medicare Part D benefits.

52. Thus, as long as the drug is on the Sponsor's formulary, and the elements of "Negotiated Price" as defined by § 423.100 are satisfied, the enrollee is entitled to the Negotiated Price ***even when the Sponsor is not paying anything for the prescription in question***. This extends to formulary drugs with restrictions such as prior authorization, step therapy, and quantity limits. As long as the drug in question is a covered drug (on the formulary), the enrollee is legally entitled to the Negotiated Price.

53. Even if the Sponsor does not cover the drug, i.e., help pay for their part of the cost of the prescription, the enrollee is only obligated to pay at most 100% of the Negotiated Price, ***and not the full retail price***, such as the price paid by an uninsured customer.[26] See e.g., Aetna EOC 2016 (Exhibit D), pg. 8 (Aetna's plan explains that enrollees must get their prescriptions filled at a network pharmacy in order for Aetna "to cover (help you pay for) them").[27]

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[26] For example, if the Sponsor (or Sponsor's PBM)—using its market power—negotiates a price of $50 for a drug, the Negotiated Price is $50. Assume further that the retail price of this same drug is $75. Finally, assume that one of the Sponsor's beneficiaries seeks to purchase the drug, but under the terms of the plan, the Sponsor is not obligated to pay anything as the result of an unmet restriction. In this situation, the beneficiary should get the benefit of the Negotiated Price and pay $50. The beneficiary should not be required to pay the $75 retail price.

[27] See also Exhibit E, pg. 8.

54. To be sure, the requirement to provide Negotiated Prices for formulary drugs with unmet requirements is not just Relator's interpretation of the statutes, rules, and regulations; it is the interpretation stated by CMS in its guidance to Plan Sponsors.

55. To better ensure that plans provide all of the required benefits, CMS provides an Evidence of Coverage (EOC) Template (see Exhibit E) that the Plan Sponsor either must use or request permission from CMS if they seek alternate wording.[28] For example, the 2016 EOC Template makes clear the following:

a. "Your '**full cost**' is usually lower than the normal full price of the drug, since **our plan has negotiated lower costs for most drugs**." (emphasis added) (pg. 68).

b. "You may pay the full cost of the prescription because you find that the drug is not covered for some reason. For example, the drug may not be on the plan's List of Covered Drugs (Formulary); or it could have a requirement or restriction that you didn't know about or don't think should apply to you. If you decide to get the drug immediately, you may need to pay the full cost for it." (pg. 90).

56. As the EOC Template demonstrates, Sponsors negotiate for lower costs, and those lower costs—the Negotiated Prices—represent the full cost an enrollee is at most responsible for regarding any drug on the Sponsor's formulary.

V. FRAUD ALLEGATIONS

57. Defendants routinely deprived a large number of beneficiaries access to Negotiated Prices in a manner that completely undercut the purpose, and violated the requirements, of Part D. Meanwhile, each month, Defendants falsely certified compliance with Part D's laws and regulations. More importantly, each month, Defendants submitted claims for capitated payments for each of Defendants' beneficiaries, including those beneficiaries who were flatly denied Negotiated Prices.[29]

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[28] See, e.g., Medicare Marketing Guidelines, pg. 75 (Exhibit S).
[29] See Exhibits A, B, and C for a more detailed overview.

58. This conduct violated the FCA. By way of example, if a beneficiary covered by Defendants had only one prescription to fill in a given month, and in connection with that prescription, the beneficiary was denied access to Defendants' Negotiated Prices (such that the beneficiary paid the full retail price), CMS did not receive even a sliver of what it bargained for. Meanwhile, Defendants billed, and CMS paid Defendants, the full capitated payment for that beneficiary. That is a material violation of the FCA.

59. The situations of Mr. Hindin and his wife, Dr. Isabelle Hindin ("Dr. Hindin"), are illustrative "real life" examples of how Defendants' failure to provide Negotiated Prices led to CMS being defrauded.

a. <u>Mr. Hindin's Need For Sleep Medication</u>

60. For over 20 years, Mr. Hindin has been suffering both from heart disease as well as two neuropathic ("nervous system") conditions: (i) neuropathic pain syndrome/neuropathy—a condition that flares up without any obvious trigger and can cause persistent, burning pain; and (ii) myofascial pain syndrome with autonomic features—a condition where the afflicted muscles are especially sensitive and experience persistent, deep pain when triggered.[30] In Mr. Hindin's case, his facial muscles suffer from myofascial pain syndrome.

61. Left untreated, these neuropathic conditions deprive Mr. Hindin of proper sleep to such an extent that they can cause him to suffer "Atrial Fibrillation," which is a heart disease that is also the most serious of his chronic ailments. Atrial Fibrillation is an irregular heartbeat that heightens Mr. Hindin's risks for strokes, heart failure, and blood clots.[31] Mr. Hindin has suffered

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[30] https://www.healthline.com/health/neuropathic-pain; https://www.mayoclinic.org/diseases-conditions/myofascial-pain-syndrome/symptoms-causes/syc-20375444
[31] https://www.mayoclinic.org/diseases-conditions/atrial-fibrillation/symptoms-causes/syc-20350624 ("Atrial fibrillation is an irregular and often rapid heart rate that can increases the risk of strokes, heart failure and other heart-related complications. A major concern with atrial fibrillation is the potential to develop blood clots within

severe episodes of Atrial Fibrillation, leading him to hospital emergency rooms on multiple occasions.

62. Consequently, Mr. Hindin was prescribed the sleeping medications Zolpidem Tartrate ("Zolpidem"—to be used nightly) and Zaleplon (to be used as required).[32] Absent insurance, both medications were prohibitively expensive for Mr. Hindin, who was not employed at the time the medications were prescribed.

63. Fortunately, Mr. Hindin became eligible for Medicare in 2015 and was able to apply for Medicare Part D coverage. Thus, instead of having to pay the non-negotiated retail cash price offered to the general public for Zolpidem (approximately $38.30 per prescription) and Zaleplon (approximately $44.89 per prescription), Mr. Hindin could either pay the full Negotiated Price (approximately $3.72 per prescription) or just a portion of it, depending on his co-pay burden.[33]

64. After gaining eligibility for Part D insurance coverage, Mr. Hindin reviewed Part D coverage plans offered by various Sponsors. He selected Aetna's "Medicare Plan Rx Saver PDP" (the "Rx Saver Plan") because it covered all of his medicine at affordable prices. And, since he qualified for "Extra Help" by way of the Low-Income Subsidy ("LIS"), his Zolpidem and Zaleplon co-pay was reduced from the Negotiated Price (approximately $3.72) to just $1.20.

65. He then selected Walmart as his pharmacy because Aetna listed Walmart as a "Preferred Pharmacy" and they offered even lower prices for many of his medications.

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the upper chambers of the heart. These blood clots forming in the heart may circulate to other organs and lead to blocked blood flow (ischemia). Although atrial fibrillation itself usually isn't life-threatening, it is a serious medical condition that sometimes requires emergency treatment.")

[32] Zolpidem: https://www.webmd.com/drugs/2/drug-9690/ambien-oral/details; Zaleplon: https://www.webmd.com/drugs/2/drug- 17524/zaleplon-oral/details.

[33] Exhibit G (Mr. Hindin paid $1.20 for the Zolpidem, and "Extra Help" paid $2.52).

b. Aetna Deprived Mr. Hindin Of The Negotiated Prices

66. Mr. Hindin's coverage started on May 1, 2015. In May and June 2015, Mr. Hindin filled two prescriptions for Zolpidem 10mg, paying a co-pay of $1.20 for each prescription.

67. Then, on July 2015, a Walmart pharmacist informed Mr. Hindin he needed prior authorization for his Zolpidem, or he would need to pay the cash price of $37.78.[34] This was surprising news. Mr. Hindin had already been granted prior authorization and had been filling his prescriptions without any issues. In fact, Mr. Hindin believed his physician submitted—***and Aetna granted***—his prior authorization paperwork before he filled his prescription in July. Regardless, since Zolpidem was on Aetna's formulary, he should not have paid more than the Negotiated Price, i.e., approximately $3.72.

68. Mr. Hindin contacted Aetna to report his denied coverage and was informed by a representative that his paperwork seemed to be lost, but that they were in the process of resolving the issue. He was also advised to keep his receipts so Aetna could later reimburse him for paying the retail cash price.

69. Unfortunately, the same thing happened the following month: Mr. Hindin went to fill his prescription but was told he needed to pay the cash price because he did not have prior authorization. On this occasion, Mr. Hindin paid the $37.78, believing Aetna would reimburse him in the near future. He again contacted Aetna and was again informed they were in the process of resolving the problem.

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[34] The prices for both sleep medications fluctuated slightly during the course of Mr. Hindin's relationship with Aetna.

70. This cycle repeated for the next 15 months, as Mr. Hindin was forced to pay the cash price to Walmart each time through November 2016. During this time, the total amount he paid nearly exceeded two months of his income as a retiree.[35]

71. Finally, on November 2016, Aetna belatedly restored his prior authorization for both drugs. The payments Mr. Hindin made while Aetna denied his coverage are listed below:

Date	Payments if prescription were covered	Actual Payments to Walmart	Drug (30-day supply)
08/10/15	$1.20	$37.78	Zolpidem
09/11/15	$1.20	$37.50	Zolpidem
10/11/15	$1.20	$37.50	Zolpidem
11/10/15	$1.20	$37.50	Zolpidem
12/11/15	$1.20	$37.50	Zolpidem
01/11/16	$1.20	$37.50	Zolpidem
02/11/16	$1.20	$38.30	Zolpidem
03/16/16	$1.20	$38.30	Zolpidem
04/12/16	$1.20	$38.30	Zolpidem
05/12/16	$1.20	$38.30	Zolpidem
05/19/16	$1.20	$44.89	Zaleplon
06/12/16	$1.20	$38.30	Zolpidem
07/12/16	$1.20	$38.30	Zolpidem
08/14/16	$1.20	$38.30	Zolpidem
09/03/16	$1.20	$44.99	Zaleplon
09/15/16	$1.20	$38.30	Zolpidem
10/15/16	$1.20	$38.30	Zolpidem
11/15/16	$1.20	$38.30	Zolpidem
Total	**$21.60**	**$698.16**	

c. Mr. Hindin Fought To Receive the Reimbursement Aetna Owed Him.

72. Aetna has a "Part D coverage decisions and appeals"[36] process through which an enrollee can ask for reimbursement after paying the cash price for a drug on their formulary—the

[35] Mr. Hindin started collecting $445 a month in Social Security benefits on May 2016.
[36] Aetna EOC 2016, Pgs. 98-112, Aetna structures their process in accordance with the Rules and Regulations, 42 U.S.C. §§ 423.560 – 423.564.

same situation that Mr. Hindin faced with his Zolpidem and Zaleplon prescriptions.[37] The process is described below:

a. First, enrollees are encouraged to contact Aetna by calling, writing, or faxing their particular request to a representative, along with any necessary or helpful documentation.[38]

b. After a review, if Aetna denies all or part of the request, Aetna sends the enrollee a letter to explain the company's decision and to inform the beneficiary of their right to appeal.[39]

c. Aetna calls the first appeal the "Level 1 Appeal" or "Redetermination." Level 1 Appeals/Redeterminations are reviewed by a different set of Aetna reviewers than those who provided the original decision, in order to ensure the previous reviewers were "following all of the rules properly."[40] The appeal process requires that the enrollee submit a written request for the new reviewers to review.[41]

d. If Aetna rejects all or part of the Level 1 Appeal/Redetermination, then the enrollee can request a "Level 2 Appeal," which is conducted by an independent organization ("Independent Review Entity" or "IRE") that is hired by Medicare.[42] When this next appeal process begins, Aetna is supposed to send the information they have about the enrollee's appeal (the "case file") to the IRE.[43] Enrollees have the right to ask Aetna for a copy of the case file, and to supplement it with additional information.[44]

e. If the IRE upholds Aetna's decision, then the enrollee can ask for a "Level 3 Appeal" in which an Administrative Law Judge reviews the matter and issues a decision.[45]

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[37] Aetna's "Evidence of Coverage" manual, which—as mentioned—is almost entirely taken from CMS's EOC template that they make accessible to all potential insurers (see Exhibit E) and which provides enrollees with a detailed overview of their benefits, also provides a review of the "coverage decision" and "appeals" process in multiple sections, including: Chapter 5, Section 2 ("How to ask us to pay you back"), Pg. 75 (Exhibit E, pg. 91); Chapter 5, Section 3 ("We will consider your request for payment and say yes or no"), Pg. 76 (Exhibit E, pg. 92); Chapter 7, Section 4 ("Coverage Decisions and Appeals"), pg. 98 (Exhibit E, pg. 110); and Chapter 7, Section 5 ("Your Part D prescription drugs: How to ask for a coverage decision or make an appeal"), pg. 100 (Exhibit E, pg. 112); and Chapter 7, Section 6 ("Taking your appeal to Level 3 and beyond"), pg. 112 (Exhibit E, pg. 125).
[38] Aetna EOC 2016, pg. 104 (Exhibit E, pg. 117).
[39] Aetna EOC 2016, pg. 76 (Exhibit E, pg. 92).
[40] Aetna EOC 2016, pg. 99 (Exhibit E, pg. 111).
[41] Aetna EOC 2016, Pg. 107 (Exhibit E, pg. 120).
[42] Aetna EOC 2016, pg. 110 (Exhibit E, pgs. 123-124).
[43] Aetna EOC 2016, pg. 110 (Exhibit E, pgs. 123-124).
[44] Aetna EOC 2016, pg. 110 (Exhibit E, pgs. 123-124).
[45] Aetna EOC 2016, pg. 111. There are a few more levels involved, see Pgs. 111-113, but Mr. Hindin's reimbursement was granted by the ALJ, so it is not necessary to provide the rest of the process to review Mr. Hindin's allegations.

73. Mr. Hindin engaged the coverage decision process in July 2015. After his prior authorization was restored, Mr. Hindin re-engaged the process on December 10, 2016, this time by writing a letter requesting reimbursement for the $698.16 he paid for his sleep medication (Exhibit H).

74. Less than a week later, on December 16, 2016, Aetna responded that they would (i) repay his "out of pocket costs" minus any co-pay, co-insurance, or deductible; and (ii) reimburse the claims and pay them at the "contract rate" for the prescriptions filled between January 2016 and November 2016 (Exhibit I). Aetna then provided Mr. Hindin three separate checks for a grand total of $29.04.[46]

75. On December 27, 2016, Mr. Hindin wrote to Mark Bertolini, Aetna's (then) CEO, to inquire about his coverage and the reimbursement funds (Exhibit J). This letter functioned as Mr. Hindin's Level 1 Appeal, given that he was expressing disagreement with the amount that he was reimbursed.

76. On January 27, 2017, Mr. Hindin received a response from Carol Strickland, a Manager in Aetna's Executive Resolution Team (Exhibit K). She stated that she was speaking for Mr. Bertolini to inform Mr. Hindin that Aetna was refusing to provide further reimbursement and that they sent his appeal to Maximus Federal Services ("Maximus") for review—a notification to Mr. Hindin that a Level 2 Appeal had been triggered[47] on his behalf.[48]

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[46] $15.64, given on December 16; $0.80, given on December 19; and $12.60, given on December 20. Mr. Hindin did not cash or deposit these checks.

[47] As required by 42 C.F.R. § 423.568(h) **Effect of failure to meet the adjudicatory timeframes**: "If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe."

[48] A third-party entity CMS contracts with for its independent reviews of Part D appeals. https://www.medicarepartdappeals.com/content/about-us.

77. Separately and on the same day, Melinda Borgen—a Complaint Analyst on Aetna's Medicare Complaint Team—informed Mr. Hindin via letter that they were declining further reimbursement and that his appeal had been sent to Maximus (Exhibit L). Her letter incorrectly stated Zolpidem was a "non-formulary" drug, in spite of the fact that Aetna explicitly included Zolpidem on their formulary, which was one of the main reasons Mr. Hindin chose Aetna as his insurer.

78. Four days later, on January 31, 2017, Maximus notified Mr. Hindin his appeal was denied by the IRE (Exhibit M).[49]

79. On February 10, 2017, Mr. Hindin filed a request for an appeal to an Administrative Law Judge ("ALJ"), officially triggering his Level 3 Appeal (Exhibit N). A hearing was scheduled for September 25, 2017.

80. According to Mr. Hindin, at the hearing, Dr. Alyssa Watson—Aetna's Senior Compliance Lead and expert witness—testified regarding Aetna's policies on the prices Aetna enrollees must pay. Dr. Watson claimed that Aetna enrollees in Mr. Hindin's situation ***are not*** provided access to Aetna's Negotiated Prices and instead must pay ***"the full cost"*** which has ***"nothing to do with your insurance."*** When asked what she meant by "full cost," she confirmed that she meant "**the cash price**."[50]

81. On December 6, 2017, the judge ruled in Mr. Hindin's favor (Exhibit O). The Court explained the difference between the Negotiated Price and the cash price as follows: "[Aetna]

[49] Mr. Hindin did not receive this case file until after his appeals decision, which was almost one year from the date he received notice that he lost his appeal. When he received his file, Mr. Hindin discovered it was missing critical information relevant to the reimbursement decision, including: (i) various call records to Aetna in which he asked for reimbursement; (ii) his letter to Mr. Bertolini, which contained both a grievance and direct request for reimbursement; and most importantly, (iii) a fax from his physician requesting prior authorization. Furthermore, Mr. Hindin was not informed that his case file was sent to Maximus nor that he could supplement it with materials of his choosing.

[50] Stephanie Godfrey—a lawyer within Aetna's Medicare business unit—monitored the testimony and at no point objected to Dr. Watson's statements.

negotiated with the pharmacy to charge Plan members a lower price for the medications than the price at which the pharmacy sells the medications to the general public."[51]

82. Even though Mr. Hindin was entitled to the Negotiated Price, the judge found that Mr. Hindin "had to buy the medications at the higher, general public offering price" and when Aetna finally reimbursed him, they "only reimbursed him the contract rate for the medication, not the actual sale price" that he was forced to pay for 17 months. In other words, the Court found that Mr. Hindin should not have paid more than the Negotiated Price, and Aetna should have fully reimbursed him for the difference between Aetna's Negotiated Prices and the full retail cash prices Mr. Hindin was forced to pay.

83. Furthermore, the Court made clear that Aetna was the party at fault for Mr. Hindin's overpayments. In particular, the proceedings highlighted the extent to which Aetna's policies, and its general delay in resolving issues as they arose, frustrated his ability to receive his reimbursement in a timely fashion.[52]

84. Eventually, on December 14, 2017, Aetna issued the first of three checks to reimburse Mr. Hindin for his out-of-pocket expenses. However, untold numbers of similarly-situated enrollees paid full retail cash prices and were never reimbursed. Meanwhile, Aetna pocketed capitated payments from CMS for allegedly providing insurance coverage to these enrollees.

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[51] R. Hindin, A.L.J. Appeal No.: 1-5864210931, Pg. 5 (Dep't of H.H.S. Dec. 6, 2017) (A.L.J. appeal)

[52] For example, the court noted that Mr. Hindin informed Aetna about his reimbursement requests, which "they said they would process"—testimony the court also noted was "corroborated in the calls provided by [Aetna]." R. Hindin, A.L.J. Appeal No.: 1-5864210931, Pgs. 5-6 (Dep't of H.H.S. Dec. 6, 2017) (A.L.J. appeal). Yet in spite of having these records and the legal obligation to provide them to Mr. Hindin at his request, C.F.R. 42 § 423.136(d), the court still needed to issue a subpoena asking for ***all*** copies of recorded conversations between Aetna (and CVS Health) and Mr. Hindin, due to Aetna's actions and inactions to resist complying with their obligations, thus causing months of unnecessary delay.

d. Express Scripts Also Deprives Beneficiaries of Its Negotiated Prices

85. For years, Mr. Hindin's wife, Dr. Hindin, has suffered from Fibromyalgia—a disorder that causes musculoskeletal pain and is accompanied by fatigue, sleep, memory, and mood complications—for which she was taking Zolpidem to help manage the disease's impact on her health.[53]

86. Beginning on January 1, 2018, Dr. Hindin enrolled in the Medicare Part D program with Express Scripts and selected its "Choice Plan." Unlike Aetna, Express Scripts' formulary did not (and does not) require prior authorization for Zolpidem, which factored heavily into her choice.[54] Furthermore, because of other looming health concerns, the Choice Plan's wide range of covered drugs appealed to Dr. Hindin as the most adaptable option going forward. For these reasons, she selected the Choice Plan despite it being Express Scripts' most expensive offering.

87. On April 10, 2018, Mr. Hindin went to Walgreens—an Express Scripts network pharmacy—in an attempt to fill Dr. Hindin's prescription for Zolpidem.[55] However, Express Scripts denied her coverage, citing the absence of prior authorization, even though its formulary did not require prior authorization for Zolpidem. As a result, Mr. Hindin was forced to pay the cash price of $133.89 for the medication.[56]

88. To resolve these unexpected issues with her coverage, Dr. Hindin's physician filed for prior authorization, which she received by May 9, 2018. Express Scripts then sent Dr. Hindin a letter to memorialize the good news and to inform her that "this [prior authorization] request has

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[53] https://www.mayoclinic.org/diseases-conditions/fibromyalgia/symptoms-causes/syc-20354780

[54] Express Scripts Medicare (PDP) 2018 Formulary (List of Covered Drugs), Choice Plan, pg. 31 (https://www.ohsers.org/wp-content/uploads/2018/04/2018-Express-Scripts-Medicare-Formulary.pdf); Express Scripts Medicare (PDP) 2019 Formulary (List of Covered Drugs), pg. 39 (https://assets.system.tamus.edu/files/benefits/pdf/EGWPFormulary.pdf).

[55] Mr. Hindin was authorized to pick up Dr. Hindin's prescriptions and to communicate Express Scripts on her behalf.

[56] The Hindins share funds.

been approved from 04/09/2018 until 05/09/2019," therefore encouraging her to "submit a request for reimbursement[.]" See Exhibit P, pg. 1. Based on this information, on May 16, 2018, Dr. Hindin submitted a request for reimbursement of $133.89.

89. Ten days later, Express Scripts sent Dr. Hindin another letter, this time to inform her it had denied her reimbursement request because "the prescriber was not eligible to prescribe [Zolpidem] on the date the drug was dispensed." See Exhibit Q, pg. 1. Express Scripts' claim was allegedly based on the prescriber's lack of a National Prescriber Information (NPI) number and Drug Enforcement Administration (DEA) number. However, Express Scripts already knew this information when they granted Dr. Hindin's (unnecessary) prior authorization. And, by virtue of being an enrollee, it should at most have charged her the Negotiated Price, not the cash price.

90. In spite of these reimbursement issues, Dr. Hindin's prior authorization was still in effect. On June 30, 2018, Dr. Hindin filled her second prescription for 90 days' worth of Zolpidem 10mg. She was correctly asked to pay $7.31 (100% of the Negotiated Price, instead of the retail cash price of $133.89).[57]

91. On July 6, 2018, Dr. Hindin sent Express Scripts a letter (i) making a second request for reimbursement, and (ii) informing it that its Notice of Denial was incorrect, referencing its May 9, 2018 letter as support for her claim.

92. On October 22, 2018, after several failed attempts to receive reimbursement, Mr. Hindin spoke directly with an Express Scripts representative (Exhibit R). On Express Scripts' behalf, the representative denied any responsibility to reimburse the over-payment, claiming that

[57] On September 22, 2018, Dr. Hindin subsequently filled her third prescription at Walgreens for 90 days' worth of Zolpidem Tartrate 10mg and paid the co-pay of $17.36 (again, the entire Negotiated Price) instead of the cash price of $133.89.

Dr. Hindin was correctly charged $133.89 rather than the Negotiated Price because "they didn't run it through [her] insurance … that's like [him] going to it without insurance at all."[58]

93. To date, Express Scripts has not provided reimbursement for Dr. Hindin's $133.89 charge for Zolpidem purchased on April 10, 2018, despite numerous phone calls and letters.

VI. FCA Violations

94. **False claims/statements**. The false claims in this case are not claims CMS paid at the pharmacy counter. In fact, by virtue of the coverage denials detailed above, CMS did not pay anything for the specific prescriptions that underly this lawsuit. But neither did Aetna or Express Scripts—which is the point. Medicare Part D was specifically designed to provide Medicare enrollees with inexpensive access to prescription drugs based on the massive bargaining power of companies like Aetna and Express Scripts. Instead of following the law and doing what CMS paid them to do, Aetna and Express Scripts wrongfully denied their enrollees access to Negotiated Prices, thereby frustrating the entire purpose of the Part D program.

95. In terms of false statements, they abound. Sponsors must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). Further, CMS regulations require all subcontracts between Sponsors and downstream entities to contain language obligating the downstream pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

96. These requirements include certifications to the accuracy, completeness, and truthfulness of all data related to the monthly capitation payments made by CMS to the Sponsor. U.S. ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 133 (E.D. Pa. 2012) (citing 42

[58] With permission, Mr. Hindin recorded the call.

C.F.R. § 423.505(k)(1)).[59] These certifications are a condition of receiving the monthly capitation payment. Id.

97. Therefore, false claims were submitted every month where (i) capitated payments were made by CMS to Aetna and Express Scripts to provide Part D coverage, (ii) Aetna and Express Scripts certified they had complied with all Part D requirements, which includes the requirement that enrollees receive the benefit of Negotiated Prices, and (iii) enrollees paid the full retail cash price at the pharmacy counter instead of defendants' Negotiated Prices for Part D covered drugs with unmet restrictions.[60]

98. **Materiality**. As noted above, the entire purpose of Medicare Part D is to make drugs more affordable to senior citizens, including by providing them with the bargaining power inherently contained in their Sponsors' Negotiated Prices.[61] Thus, if a Sponsor certifies that it has provided enrollees with Negotiated Prices as a condition of receiving the monthly capitated payments from CMS for these enrollees, but meanwhile, the Sponsor has failed to provide its Negotiated Prices, it is self-evident that the Sponsor's certification is material to its receipt of the capitated payment. Escobar at 194 (While a mere statutory requirement is not evidence of materiality, a statutory requirement central to the very purpose of a law, such as the Negotiated Prices, provides the sort of "relevant" evidence that a condition is material to the government's decision to pay.)

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[59] If the claims data has been generated by a subcontractor of a Part D plan sponsor, that entity must also certify the claims data it has generated is accurate, complete, and truthful, and must acknowledge it will be used to obtain federal reimbursement. 42 C.F.R. § 423.505(k)(3).

[60] Further, as demonstrated by the testimony of Aetna's compliance policy specialist Dr. Alyssa Watson, the situation with Mr. Hindin was not an anomaly. ***It was Aetna's policy*** not to offer Negotiated Prices to enrollees who had unmet restrictions, e.g., prior authorization. Similarly, at Express Scripts, it was the company's stated policy not "to run it through" Dr. Hindin's insurance, such that the transaction was "like [him] going to it without any insurance at all." This is sufficient for pleading purposes. Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 158 (3d Cir. 2014).

[61] Suzanna M. Kirchhoff, *Medicare Part D Prescription Drug Benefit*, Congressional Research Service, Dec. 18, 2020, pgs. 6-7 (https://crsreports.congress.gov/product/pdf/R/R40611).

99. In addition to being self-evident, the materiality of providing Negotiated Prices is expressly evident wherever one looks. A partial list of sources follows:

a. ***The enabling legislation itself expressly states that Negotiated Prices must be provided even if no benefits are payable***, which is the claim being made in this lawsuit:

> Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan…the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit.

42 U.S.C. § 1395w-102(d)(1)(A); see also 42 C.F.R. § 423.104(g)(l) ("A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary).

b. The regulations carefully define Negotiated Prices. 42 C.F.R. § 423.100.

c. The regulations specify when Negotiated Prices must be provided. 42 C.F.R. § 423.104 (g)(l).

d. Aetna itself recognized the materiality of providing Negotiated Prices, and expressly promised to provide those prices to enrollees. Aetna EOC 2016, pg. 58 ("[Y]ou must pay the full cost of your drugs until you reach the plan's deductible amount...[y]our 'full cost' is usually lower than the normal full price of the drug, since our plan has negotiated lower costs for most drugs.");[62] Aetna EOC 2016, pg. 74 ("Save your receipt and send a copy to us when you ask us to pay you back. In some situations, we may need to get more information from your doctor in order to pay you back for our share of the cost").[63] A defendant's recognition of the importance of a particular provision is highly probative evidence of materiality. Escobar at 194-195 ("[P]roof of materiality can include...evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.")

[62] See Exhibit E, pgs. 67-68.
[63] See Exhibit E, pg. 91.

e. CMS expressly encourages enrollees to use their Part D prescription drug benefit card to access Negotiated Prices. Medicare Prescription Drug Benefit Manual, Chapter 14, Section 50.4.2.

100. In addition to being a condition of payment, providing enrollees with the benefit of Negotiated Prices is a fundamental part of the bargain between CMS and Sponsors like Aetna and Express Scripts. That Negotiated Prices are fundamental to the bargain between CMS and Part D Sponsors is well and further illustrated by the "Joint Explanatory Statement" memorializing the agreements between the House and the Senate less than one month before the Part D legislation became law:

a. "The program will rely on private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies will be provided to encourage participation. Plans will determine premiums through a bid process **and will compete based on premiums and negotiated prices**."[64] (emphasis added).

b. "PDP sponsors are required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary **to assure access to negotiated prices for drugs**."[65] (emphasis added).

c. "The New Section 1860D-2 specifies the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either 'standard prescription drug coverage' or 'alternative prescription drug coverage' with at least actuarially equivalent benefits. **In both cases, access would have to be provided to negotiated prices**."[66] (emphasis added).

101. In sum, providing Negotiated Prices to enrollees is plainly a fundamental part of the bargain between CMS and Part D Sponsors and therefore is material as a matter of law. Escobar at 193 (when analogizing questions of materiality to contract law, the Court explains that a misrepresentation is material during a bargain if it "would likely induce a reasonable person to

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[64] See Exhibit F, pg. 4.
[65] See Exhibit F, pg. 21.
[66] See Exhibit F, pg. 11.

manifest his assent, or the defendant knows that for some special reason the representation is likely to induce the particular recipient to manifest his assent to the transaction." (citations omitted).

102. **Scienter**. Defendants are under a duty to understand and follow the requirements for requesting reimbursement from CMS for Medicare Part D enrollees, including the numerous provisions requiring Defendants to provide Negotiated Prices to enrollees. Heckler v. Cmty. Health Servs. of Crawford Cty., Inc., 467 U.S. 51, 63-64 (1984) ("As a participant in the Medicare program, [a provider has] a duty to familiarize itself with the legal requirements for cost reimbursement" because "[p]rotection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law"); Admiralty Condo. Ass'n, Inc. v. Dir., Fed. Emergency Mgmt. Agency, 594 F. App'x 738, 740 (3d Cir. 2014) (in upholding the lower court's dismissal of plaintiff's complaint due to failure to comply with regulations, the court cited the principle that "Men must turn square corners when they deal with the Government.") (citing Justice Holmes in Rock Island, Ark. & La. R.R. Co. v. United States, 254 U.S. 141, 143 (1920).

103. The statute here is clear:

> "Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan…the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit." 42 U.S.C. § 1395w-102(d)(1)(A). Other Part D Sponsors had no trouble understanding this requirement, and following it.

Defendants' failure to do so, at a minimum, constitutes reckless disregard of the law.

VII. COUNTS

a. Count 1: Violation of 31 U.S.C. § 3729(a)(1)(A)

104. Relator repeats and realleges the allegations set forth above as though set forth herein.

105. In violation of 31 U.S.C. § 3729(a)(1)(A), Defendants knowingly presented or caused the presentment of false or fraudulent claims for payment or approval by seeking capitated payments for beneficiaries for whom Defendants failed to provide Medicare Part D prescription drug coverage as required by law.

106. By virtue of these false or fraudulent claims that Defendants presented or caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

b. <u>Count 2: Violation of 31 U.S.C. § 3729(a)(1)(B)</u>

107. Relator repeats and realleges all of the allegations set forth above as though set forth herein.

108. In violation of 31 U.S.C. § 3729(a)(1)(B), Defendants knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims by certifying compliance with all applicable laws, regulations, and payment rules relating to the provision of Medicare Part D prescription drug coverage.

109. By virtue of the false records and statements made by Defendants, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

c. <u>Count 3: Violation of 31 U.S.C. § 3729(a)(1)(C)</u>

110. Relator repeats and realleges all of the allegations set forth above as though set forth herein.

111. As described above, Defendants have conspired to commit violations of 31 U.S.C. § 3729 (a)(l)(A) or 31 U.S.C. § 3729 (a)(l)(B).

112. All Defendants committed these acts knowing, or in deliberate ignorance or with

reckless disregard, that their actions would result in false claims upon the federal Government. These false claims caused financial damage to the federal Medicare program.

CONCLUSION

WHEREFORE, the Relator, on behalf of the United States, hereby prays that this Court:

(1) Enter judgment against Defendants holding them liable for a civil penalty of $11,000 for each violation of the False Claims Act committed by Defendants;

(2) Enter judgment against Defendants holding them liable for three times the amount of damages sustained by the United States because of the acts of Defendants;

(3) Enter judgment against Defendants awarding the Relator a percentage of the proceeds recovered by the United States as a result of this action in accordance with 31 U.S.C. § 3730(d);

(4) Enter judgment against Defendants awarding the Relator his costs and reasonable attorneys' fees for prosecuting this action in accordance with 31 U.S.C. § 3730(d); and

(5) Enter judgment against Defendants awarding any and all other relief that the Court finds to be just and equitable.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Relator hereby demands a trial by jury.

Date: January 11, 2022

Respectfully submitted,

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